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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,184	09/24/2004	Alexander D Slowey	57666WO003	7403

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/509,184	SLOWEY ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 and 17 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on July 7, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The examiner acknowledges the cancellation of claims 15 and 16. Therefore, any and all objections and/or rejections directed towards them are hereby withdrawn.

3. The provisional rejection of claims 1-3 and 7-14 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-22, 25-29, 31 and 32 of copending application 10/398,335 is hereby withdrawn as applicant has amended the claims to overcome the rejection.

4. The rejection of claims 1-14 and 17 under 35 U.S.C. 103(a) over Trofast et al. is hereby withdrawn as applicant has amended the claims to overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims a "physiologically functional derivative thereof" of the drug formoterol. It is unclear to the examiner what this means, are there derivatives of formoterol that are not physiologically functional? Please clarify.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 10, 11, 13 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/510,147. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending

applications are directed towards an aerosol composition comprising particles of formoterol, a propellant selected from 1,1,1,2-tetrafluroethane and 1,2,3,3,3-heptafluoropoprane contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer. The difference between the two is in '147 an additional compound is added. It is the position of the examiner that since the language of the instant invention recites the open language of "comprising", it can contain other ingredients, such as those taught in '147.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

Applicants claim an aerosol composition comprising particles of formoterol, a propellant selected from 1,1,1,2-tetrafluroethane and 1,2,3,3,3-heptafluoropoprane and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Trofast et al. discloses a pharmaceutical combination comprising formoterol and mometasone. Page 3, lines 14-18 teach the composition further containing a one or more pharmaceutically acceptable additives, diluents or carriers. Page 3, lines 22-27 teach that the preferred form of formoterol is the fumarate dihydrate salt and the preferred form of mometasone is the monohydrate of the furoate ester. Page 5, line 24 through page 6, line 11 teach that the composition can be inhaled from a nebulizer, pressured metered dose inhaler, or as a dry powder from a dry powder inhaler. It also teaches that a diluent or carrier such as lactose, dextran, mannitol or glucose can be added to the medicament. It also teaches that the one or more ingredients are preferably in a micronized dry powder form having a particle size of less than 10 microns. Page 6, lines 13-20 teach that when the system is a pressurized inhaler the ingredients are preferably in micronized form and that it is suspended in a liquid propellant such as P134a (tetrafluoro-ethane) and P227 (heptafluoropropane). The

propellants can also be used in combination with one or more surfactants or excipients such as ethanol. The prior art does not teach amount of drug (formoterol and mometasone) present in the composition, the ratio of the drugs to the bulking agent and a method of preparing the composition.

Ashurst et al. teaches a metered dose inhaler having all or part of its internal surfaces coated with one or more fluorocarbon polymers (abstract). Column 1, lines 50-63 of Ashurst et al. teaches that some aerosol drugs tend to adhere to the inner surfaces of inhalers and that coating the interior surfaces can reduce the problem of adhesion or deposition on the can walls.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Trofast et al. does not teach coating the interior surface of the aerosol vial with a fluorocarbon polymer.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Ashurst et al. in the invention of Trofast et al. to teach an aerosol composition comprising particles of formoterol, a propellant and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer. It is the position of the examiner that although the coated

interior surfaces of Ashurst et al. is being used for albuterol, the same holds true for any and all drugs that adhere to the interior walls of aerosol vials. If it is believed, that formoterol adheres to the interior wall of aerosol vials; it would be within reason for one of ordinary skill to apply a substance to the aerosol vials to reduce adhesion.

Response to Arguments

8. Applicant's arguments filed July 7, 2006 have been fully considered but they are not persuasive.

Applicant argues that the aerodynamic size of the bulking agents is much smaller than 1 micron as taught in Trofast et al. It is the position of the examiner that the particle size of the bulking agent taught in Trofast et al. reads on the particles size of the instant invention and is thus obvious.

Conclusion

9. Claims 1-14 and 17 remain rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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